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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,637

03/24/2004

Jun Feng

DPP-IV-5004-C2

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TAKEDA SAN DIEGO, INC.
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EXAMINER

HABTE, KAHSAI

ART UNIT

PAPER NUMBER

1624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/809,637	Applicant(s) FENG ET AL.	
	Examiner Kahsay Habte	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 15-25, 27-29, 31, 33-73 and 75-86 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 15-25, 33-73 and 75-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 27-29 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

2/12/2007, 2/1/2007, 1/23/2007, 1/8/2007, 11/15/2006, 9/26/2006, 9/7/2006 and 8/15/2006.

DETAILED ACTION

1. Claims 11-13, 15-25, 27-29, 31, 33-73 and 75-86 are pending in this application. Claims 11-12, 15-25, 33-73 and 75-86 are withdrawn from prosecution as being drawn to non-elected invention. Note that claims 25 and 58 are drawn to non-elected invention.

Response to Amendment

2. Applicant's amendment filed 2/12/2007 in response to the previous Office Action (8/11/2006) is acknowledged. Rejections of claims 1-13, 25, 27-29, 31, 58, 69-71 and 84-86 under 35 U.S.C. § 112, second paragraph (items 9a-9e) and the prior art rejections (items 5-8) have been obviated. Note that applicant's amendment introduces new issue that needs further rejection.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. Applicants have to delete in claim 13 (page 4, line 10), the phrase "or two R₁₂ are taken together to form a ring fused to or bridged to the ring formed by J, K, L and M". Note that a quinazoline ring is a bicyclic ring (benzo ring fused to 1,3-diazine ring) as drawn in claim 13 (Formula XXIX).

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 2/12/2007, 2/1/2007, 1/23/2007, 1/8/2007, 11/15/2006, 9/26/2006, 9/7/2006 and 8/15/2006 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 1624

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-15, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and claims 1, 3-15, 19-21, 23, 26-31, 33, 36, 42-43 and 55-61 of copending Application No. 10/809,636.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 of copending Application No. 10/809,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and

Art Unit: 1624

claims 8-17, 19-20, 22-25, 27, 38, 52-54, 56 and 111 of copending Application No. 10/809,635.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 13, 27-29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-16, 19-20, 28-29, 32-38 and 48 of copending Application No. 10/809,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 13, 27-29 and 31 and claims 1, 7-16, 19-20, 28-29, 32-38 and 48 of copending Application No. 10/809,638.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Guadilliere et al. WO 2000/066584 A1 (equivalent to Guadilliere et al. U.S. Pat. No.

Art Unit: 1624

6,747,035). Cited reference discloses in the US patent a compound of interest: 3-benzyl-6-bromo-3,4-dihydro-quinazolin-4-one (see column 22, lines 32-48) that is the same as applicants when applicant's Formula XXIX has the following substituents:

Q = CO; J = L = M = CH; K = C-Br; R₁ = CH₂-Phenyl; and R₂ = NH-NH₂.

10. Claims 13, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakhan et al. *Journal of Indian Chemical Society* (1987), 64 (5), 316-18. Cited reference discloses a compound of interest: 2-[(2-aminoethyl)thio]-6-iodo-3-phenylmethyl)-4(3H)-Quinazolinone that is the same as applicants when applicant's Formula XXIX has the following substituents:

Q = CO; J = L = M = CH; K = C-I; R₁ = CH₂-Phenyl; and R₂ = S-CH₂-CH₂-NH₂.

The examiner has attached an abstract of this publication from STN CAS printout that shows the prior art compound.

11. Claims 13, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Shyam et al. *Current Science* (1975), 44(16), 562-4. Cited reference discloses a compound of interest: 6-bromo-2-[[2-(diethylamino)ethyl]thio]-3-phenylmethyl)-4(3H)-Quinazolinone that is the same as applicants when applicant's Formula XXIX has the following substituents:

Q = CO; J = L = M = CH; K = C-Br; R₁ = CH₂-Phenyl; and R₂ = S-CH₂-CH₂-NEt₂.

The examiner has attached an abstract of this publication from STN CAS printout that shows the prior art compound.

Art Unit: 1624

12. Claims 13, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Tiwari et al. *Indian of Journal of Pharmaceutical Sciences* (1978), 40(2), 40-3. Cited reference discloses a compound of interest: N-[[6,8-dibromo-3-[2-(3,4-dihydrophenyl)ethyl]-3,4-dihydro-4-oxo-2-quinazolinyl]methyl]-Benzamide that is the same as applicants when applicant's Formula XXIX has the following substituents: Q = CO; J = L = CH; M = K = C-Br; R₁ = CH₂-CH₂-3,4-dihydroxyphenyl; and R₂ = -CH₂-NHCO-Phenyl (R_m = phenyl).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 27 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Bergnes et al. U.S. Pat. No. 7,161,002. Cited reference teaches a compound of interest: 2-(1-amino-2-methylpropyl)-7-chloro-3-(phenylmethyl)-4(3H) Quinazolinone (see column 29, lines 2-30) that is the same as applicants when applicant's Formula XXIX has the following substituents:

Q = CO; J = L = M = CH; K = C-Cl; R₁ = CH₂-Phenyl; and R₂ = CH(NH₂)-isopropyl.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 27-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenard et al. *J. Med. Chem.* **2001**, 44, 1710-1717. Cited reference at page 1711 discloses many quinazolinone compounds e.g. see compounds 6, 7, 10-16 that are almost the same as applicants when applicants' Formula XXXIX has the following substituents:

R_1 = phenyl substituted with chloro; $U = CH_2$; $R_2 = CH_2-NH-CH_2$ -substituted phenyl; and $R_{12} = fluoro$.

The only difference between applicants' compounds and the prior art compounds is that in the definition of R_1 . The phenyl substituents of the prior art compounds are directly linked to the quinazoline ring (R_1 = chloro-substituted phenyl), but applicants require R_1 to be CH_2 -phenyl. Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. The homologue is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a

Art Unit: 1624

specific teaching to add or remove methyl groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *In re Fauque*, 121 USPQ 425; *In re Druey*, 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. See also MPEP 2144.09, second paragraph.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 27-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 13 or elsewhere in the claims, the terms "aldehyde", "amide", "ester", and "ketone" are not clear. Said terms are molecules, but not moieties. One skilled in the art would consider these terms as molecules and not substituents or moieties.

b. In claim 13 in the definition of R₁₂, the phrase "each R₁₂carbonyl group,oxo," is not clear. Oxo and carbonyl are recited as substituents for example on alkyl group. How is carbonyl substituent substituted on the alkyl group? Do applicants mean

Art Unit: 1624

an oxo group substituted on alkyl? Note that carbonyl (C=O) is different from an oxo group (=O). If a carbonyl is substituted on alkyl, the molecule becomes charged, because of the carbon atom that bears the oxo group.

c. In claim 13, the term "comprising" is an open-ended language. It is recommended that applicants delete said term from the claims.

Response to arguments

Applicant's argument filed 2/12/2007 has been fully considered but it is not persuasive.

Applicants indicate that they have support in the specification, but the examiner disagrees with applicants. First of all, the terms "comprising" or "comprise" are an open-ended language. The claims with said terms remain indefinite, since one skilled in the art would not know if other substituents, atoms, compounds, composition etc. are included or not. What other atoms are present beside the basic nitrogen atom?

d. In claim 1 or elsewhere in the claim, the phrase "V comprises a primary, secondary or tertiary amine" is indefinite. What is covered and what is not? What is present in the primary amine except the N? It is recommended that applicants recite specific amines. Note that the term "comprises" is also an open-ended language.

Unless specific amines are recited, the presence of any nitrogen in the definition of R₂ can be considered as a prior art compound.

Response to arguments

Applicant's argument filed 2/12/2007 has been fully considered but it is not persuasive.

See above.

e. In claim 1 or elsewhere in the claims, the term "thio" is a generic one, indicating the presence of sulfur in some form. As a substituent, it has no one single generally accepted meaning. There could be intended thioxo (=S) or mercapto (-SH). It can also denote replacement by S of some other atom (normally, oxygen or carbon) as in "thioalkoxy", where O is replaced by S.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1624

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kahsay Habte', is positioned above the printed name.

Kahsay Habte
Primary Examiner
Art Unit 1624

March 13, 2007